PATENTS 13

### THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
D'AMATO ET AL.	) Art Unit: 1616	
Serial No. 09/780,650	) Examiner: BADIO, B. )	RECEIVED
Filed: FEBRUARY 12, 2001	, ) )	OCT 0 1 2004
For: ESTROGENIC COMPOUNDS AS	) )	OFFICE OF PETITIONS

#### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants filed an exact copy of this Supplemental Information Disclosure Statement on April 1, 2004. In an Office Communication mailed September 15, 2004, the Examiner indicated that the Supplemental Information Disclosure Statement submitted on April 1, 2004 has been placed in the file, but the information therein has not been considered. Applicants file herewith a Request for Continued Examination and a Petition to Withdraw from Issue in order to facilitate the consideration of the art previously submitted. Applicants have not enclosed additional copies of the articles cited pursuant to the Examiner's statement that the information previously submitted has been placed in the application file. The citation of information on the attached Form PTO/SB/08A, "List of Art Cited by Applicant" is made pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98.

Related applications are listed on the attached Supplemental Appendix A. Applicants respectfully request that the Examiner review the applications listed in Appendix A, initial Appendix A in the appropriate spaces, and return a copy of the initialized Appendix to Applicants.

I hereby certify that this correspondence is being hand delivered to the Commissioner for Patents,

P.O. Box 1450, Alexandria, VA 22313-1450, on September 29, 2004.

ATLLIB02 168542.1

The citation of this information does not constitute an admission of priority or that any cited item is available as a reference, or a waiver of any right the applicant may have under applicable statutes, Rules of Practice in patent cases, or otherwise.

Respectfully submitted.

Pobert E. RA

Robert E. Rachards, Reg. No. 29,105

KILPATRICK STOCKTON LLP 1100 Peachtree Road, Suite 2800 Atlanta, Georgia 30309-4530 (404) 815-6500

Our Docket: 05213-0493 (43170-253692)

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In re Applic	ation of:	)
D'AMATO	ET AL.	) Art Unit: 1616
Serial No.	09/780,650	) Examiner: BADIO, B.
Filed:	FEBRUARY 12, 2001	)
	ROGENIC COMPOUNDS AS ANTI- OTIC AGENTS	)

APPENDIX A

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**OFFICE OF PETITIONS** 

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants respectfully request that the Examiner review the below-listed patent applications. Please review and initial each listed application and return a copy of the initialed Supplemental Appendix A to the Applicants.

The serial numbers of the below-listed U.S. patent applications are listed on this form as provided in MPEP §609(D), rather than a PTO-1449 form, to avoid the serial numbers of the pending U.S. patent applications being published on any patent that may issue from this application. Applicants do not waive the confidential nature of any of the below-listed patent applications.

 _ 1.	U.S. Application Serial No. 09/641,327 filed August 18, 2000
 _ 2.	U.S. Application Serial No. 09/644,387 filed August 23, 2000
 _ 3.	U.S. Application Serial No. 09/779,331 filed February 8, 2001
 _ 4	U.S. Application Serial No. 09/899,702 filed July 5, 2001
 _ 5	U.S. Application Serial No. 09/939,208 filed August 24, 2001
6	U.S. Application Serial No. 10/077,142 filed February 15, 2002

Our Docket: 05213-0493 (43170-253692) Filed: February 12, 2001

 _ 7	U.S. Application Serial No. 10/080,076 filed February 21, 2002
 _ 8	U.S. Application Serial No. 10/281,831 filed October 25, 2002
 9	U.S. Application Serial No. 10/354,921 filed January 30, 2003
 _10	U.S. Application Serial No. 10/354,927 filed January 30, 2003
 _11	U.S. Application Serial No. 10/375,890 filed February 27, 2003
 12.	U.S. Application Serial No. 10/610,748 filed July 1, 2003
 _ 13.	U.S. Application Serial No. 10/617,150 filed July 10, 2003
 14.	U.S. Application Serial No. 10/635,846 filed August 5, 2003
 _ 15	Unassigned U. S. Application filed February 27, 2004 under Attorney Docket No: 05213-3001 (43170-295490)

Respectfully Submitted,

By:

Robert E. Richards Reg. No. 29,105

KILPATRICK STOCKTON LLP 1100 Peachtree Road **Suite 2800** Atlanta, Georgia 30309/4530 (404) 815-6500

Our Docket: 052130-0493 (43170-253692)

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## **INFORMATION** STATEMENT BY APPLICANT

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Compl	lete if Known
Application No.	09/780,650
Filing Date	02/12/2001
First Named Inventor	D'Amato
Group Art Unit	1616
Examiner Name	Badio, Barbara P.
Attorney Docket Number	05213-0493 (43170-253692)

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Compl	ete if Known
Application No.	09/780,650
Filing Date	02/12/2001
First Named Inventor	D'Amato
Group Art Unit	1616
Examiner Name	Badio, Barbara P.
Attorney Docket Number	05213-0493 (43170-253692)

08/12/2003

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Complete if Known SEP 2 9 2004 25 09/780,650 Application No. Substitute for Form 1449/A/PTO Filing Date 02/12/2001 INFORMATION DISCL First Named Inventor D'Amato STATEMENT BY 1616 Group Art Unit (use as many sheets as necessary) **Examiner Name** Badio, Barbara P. 05213-0493 (43170-253692) 3 of 31 Attorney Docket Number Sheet FOREIGN PATENT DOCUMENTS Date of Publication Foreign Patent Document Pages, Columns, Lines, Where T۴ Examiner Cite of Cited Document Kind Code Relevant Passages or Name of Patentee or Initials MM-DD-YYYY Relevant Figures Appear Office3 Number<sup>4</sup> (if known) Applicant of Cited Document 46 DE 1907330 Sandoz Ltd. (Identifier only) 10/23/1969 47 DE VEB Jenapharm 09/10/1970 No 2 004 516 48 DE 27 57 157 Schering AG 12/19/1977 DE 3625315 Schering A.-G (Identifier only) 01/28/1988 49 50 **EPO** 0166937 A2 Abbott Laboratories 08/01/1986 51 857,080 Syntex S.A. 12/29/1960 GB 52 GB 857,081 Syntex S.A. 12/29/1960 GB Takeda et al. 07/02/1980 53 1,570,597 В DAINIPPON PHARM CO LTD 54 JP 42-928 01/18/1967 (abstract only) No 55 JP 39-5480 В Teikoku Hormone Mfg. Co. No 08/03/1999 56 JP 11-209322 Lilly & Co Eli (Elil) 08/06/1983 No 57 ЛР 58-131978 Research Development Corp. of 04/21/1988 58 JP 63090763 Japan (Abstract only) Examiner Date Signature Considered

'Unique citation designation number. 'See attached Kinds of U.S. Patent Documents. 'Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 'For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 'Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 'Applicant is to place a check mark here if English language translation is attached.

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STATEMENT BY APPLICANT	Group Art Unit	1616		
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quired to respond to a collection of information usess it commins a valid OMB control number · Under the Paperwork Reduction Act of Complete if Known 09/780,650 Application No. Substitute for Form 1449/A/PTO 02/12/2001 Filing Date INFORMATION DE First Named Inventor D'Amato STATEMENT BY APPLY 1616 Group Art Unit (use as many sheets as necessary) Badio, Barbara P. **Examiner Name** 05213-0493 (43170-253692) Attorney Docket Number 5 of 31 Sheet FOREIGN PATENT DOCUMENTS Date of Publication Pages, Columns, Lines, Where Foreign Patent Document Cite Examiner of Cited Document Relevant Passages or Name of Patentee or Kind Code No.1 Relevant Figures Appear Initials MM-DD-YYYY Applicant of Cited Document Office3 Number<sup>4</sup> (if known) 07/08/1999 SRI International A3 72 99/33858

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	75	Author: Title: Lilopris	tone/(1-[4-(Dimethylam 9-diene-3-one; AK 9873	ino)phenyl]-17-	-hydroxy-17-(3-hydroxy-1-pr	openyl)
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'Unique citation designation number. 'See attached Kinds of U.S. Patent Documents. 'Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 'For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 'Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 'Applicant is to place a check mark here if English language translation is attached.

Date:

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Complete if Known 09/780,650 Application No. Substitute for Form 1449/A/PTO 02/12/2001 Filing Date INFORMATION DIS D'Amato First Named Inventor STATEMENT BY APPI 1616 Group Art Unit (use as many sheets as necessary) Badio, Barbara P. **Examiner Name** Attorney Docket Number 05213-0493 (43170-253692) of Sheet 11 31 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner T Cite item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials No. publisher, city and/or country where published Title: Simple Approach to Measure Metabolic Pathways of Steroids in Living Cells Author: CASTAGNETTA, L. et al. 110 Journal of Chromatography Pages: 25-39 12/06/91 Vol/Iss: 572 Date: Author: CHASSEROT-GOLAZ et al. Title: Biotransformation of 17.beta.-hydroxy-11.beta.-(4-dimethylaminophenyl) 111 17.alpha.1-propynyl-estra-4,9-diene-3-one (RU486) in Rat Hepatoma Variants Publ: (Identifier only) Biochemical Pharmacology Vol/Iss: 46 (11) Pages: 2100-2103 Date: 1993 Title: A New Synthetic Route to 2- and 4-Methoxyestradiols by Nucleophilic Substitution 112 Author: CHEN et al. Publ: Steroids 5 4 1 Pages: 63-66 Date: 01/1986 Vol/Iss: 47 (1) Title: Synthesis of 11.beta.-(4-dimethylaminophenyl)-17.beta-hydroxy-17.alpha.- (1-Author: CHEN et al. 113 propynyl) estra-4, 9-dien-3-one (RU486) (Identifier only) Publ: Nanjing Yaoxueyuan Xuebao Pages: 282-285 Date: 1986 Vol/Iss: 17 (4) Title: Novel Total Synthesis of (+)-Estrone 3-Methyl Ether, (+)-13βEthyl-3-Author: COHEN et al. 114 methoxygona-1,3,5(10)-trien-17-one, and (+)-Equilenin 3-Methyl Ether Publ: The Journal of Organic Chemistry Pages: 681-685 Date: 03/21/75 Vol/Iss: 40 (6) Title: The Structure and Function of Estrogens. XI. Synthesis of  $(+/-)-7(8-11\alpha)$ Author: COLLINS et al. 115 abeo-Estradiol and its 9,11-Didehydro Derivative Publ: Aust. Journal of Chemistry Vol/iss: 45 (1) Pages: 71-97 Date: 1992 Title: Applications of N,N-Dimethylhydrazones to Synthesis. Use in Efficient, Positionally Author: COREY et al. 116 and Stereochemically Selective C-C Bond Formation; Oxidative Hydrolysis to Carbonyl Compounds Publ: Tetrahedron Letters Pages: 3-6 Date: 1976 Vol/Iss: 1

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Complete if Known 09/780,650 Application No. Substitute for Form 1449/A/PTO Filing Date 02/12/2001 INFORMATION DISCL First Named Inventor D'Amato STATEMENT BY APPI 1616 Group Art Unit (use as many sheets as necessary) Badio, Barbara P. **Examiner Name** 05213-0493 (43170-253692) Attorney Docket Number Sheet 16 of 31 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner Cite T۴ item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials No.1 publisher, city and/or country where published Title: Reaction of Eugenol with Synthesis Gas. Synthesis of 5,6,7,8-Tetrahydro Author: GASLINI et al. 145 -3-methoxy-2-napthol Publ: Journal of Organic Chemistry Pages: 1177-1180 Date: 05/1964 Vol/Iss: 29 (5) Title: Tumor Growth and Neovascularization: An Experimental Model Using the Rabbit 146 Author: GIMBRONE, M.A. et al. Comea Publ: Journal of the National Cancer Institute Vol/lss: 52(2) Pages: 413-427 Date: 02/74 Title: Tumor dormancy in vivo by Prevention of Neovascularization 147 Author: GIMBRONE, M.A. et al. Journal of Experimental Medicine Pages: 261-276 Date: 1972 Vol/lss: 136 Title: Synthesis and Pharmacological Evaluation of 8αEstradiol Derivatives 148 Author: GONZALEZ et al. Publ: Steroids Pages: 171-187 Date: 9/1982 Vol/Iss: 40 (2) Title: Modulation of Solid Tumor Growth in vivo by bFGF (Abstract only) Author: GROSS, J.L. et al. 149 Proceedings of the American Association of Cancer Research Pages: 79 Date: 03/90 Vol/Iss:31 Title: The Effect of Estradiol on Candida albicans Growth Author: GUJJAR et al. 150 Annals of Clinical and Laboratory Science Pages: 151-156 Vol/Iss: 27 (2) 1997 Title: Thalidomide-A Therapy for the Immunological Consequences of HIV Infection? 151 Author: GUNZLER, V. Publ: Medical Hypothesis Pages: 105-109 Date: 10/89 Vol/Iss: 30 (2)

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Complete if Known Application No. 09/780,650 Substitute for Form 1449/A/PTO 02/12/2001 Filing Date INFORMATION DES First Named Inventor D'Amato STATEMENT BY APP 1616 Group Art Unit (use as many sheets as necessary) **Examiner Name** Badio, Barbara P. 05213-0493 (43170-253692) Attorney Docket Number of Sheet 21 31 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner Cite T۴ item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials No. publisher, city and/or country where published Title: Avascular and Vascular Phases of Tumour Growth in the Chick Embyo Author: KNIGHTON, D. et al. 180 British Journal of Cancer 1977 Pages: 347-356 Date: Vol/Iss: 35 Title: Studies in Antifertility Agents. 11. Secosteroids. 5. Synthesis of 9,11-Secoestradiol Author: KOLE et al. 181 Journal of Medicinal Chemistry Pages: 765-766 Date: 1975 Vol/Iss: 18 (7) Title: Steroids, XXIII. Synthesis of 2- and 4-hydroxy and 2,4-dihydroxy derivatives of 182 Author: KOVACS et al. estrone and estradiol (Abstract only) Publ: Acta Phys.Chem. Pages: 287-290 Date: 1973 Vol/Iss: 19 (3) Title: Activation and Regioselective Ortho-Functionalization of the A-Ring of Author: LEBRAS, J. et al. 183 B-Estradiol Promoted by "Cp\*Ir": An Efficient Organometallic Procedure for the Synthesis of 2-Methoxyestradiol Publ: Organometallics Pages: 1765-1771 Vol/iss: 16 Date: 1997 Title: Author: LEWIS, Richard J. Publ: Hawley's Condensed Chemical Dictionary Vol/Iss: Pages: 577 Date: 01/1993 Title: 185 Author: LEWIS, Richard J. Publ: Hawley's Condensed Chemical Dictionary Vol/Iss: Pages: 128-129 Date: 01/1993 Title: (DN 103:65176) Catechol Formation of Fluoro- and Bromo-substituted Estradiols by Author: LI, J., et al. Hamster Liver Microsomes. Evidence for Dehalogenation. (Abstract only) Publ: CAPLUS; Molecular Pharmacology Vol/Iss: 27 (5) Pages: 559-565 Date: 1985

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Substitute for Form 1449/A/PTO  SUBSTITUTE   Application No.   09/780,650   Filling Date   02/12/2001   First Named Inventor   D'Amato   Group Art Unit   1616   Examiner Name   Badio, Barbara P.  Sheet   22   of   31   Attorney Docket Number   05213-0493 (43170-253692)  OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS  Examiner Initials   No.   Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(5), volume-issue number(8), publisher, city and/or country where published  187   Author: LICHTENAUER et al.   Title: Zur Behandlung des Prostata-Karzinoms  Publ: Deutsches medizinisches Journal   Vol/Iss: 23   Pages: 248-249   Date:   01/1972    188   Author: LIEN, W. et al.   Title: The blood supply of experimental liver metastases. II. A Microcirculatory study of normal and tumor vessels of the liver with the use of perfused silicone rubber normal and tumor vessels of the liver with the use of perfused silicone rubber   Publ:   Surgery   Vol/Iss: 68 (2)   Pages: 334-340   Date:   08/1970    189   Author: LIMANTSEV et al.   Title: Effect of some estrogen structural analogs on the development of the mouse embyte (Abstract only)   Publ:   Akush Jinekol.   Vol/Iss: 68   Pages: 55-56   Date:   1982	T <sup>6</sup>
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Complete if Known Application No. Substitute for Form 1449/A/PTO 09/780,650 Filing Date 02/12/2001 INFORMATION DYSC First Named Inventor D'Amato STATEMENT BY APPLICANT Group Art Unit 1616 (use as many sheets as necessary) **Examiner Name** Badio, Barbara P. Attorney Docket Number 05213-0493 (43170-253692) Sheet 24 of 31 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner Cite T۴ item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials No. publisher, city and/or country where published Title: Tubulin as a Therapeutic Target (Abstract only) Author: MILLER, Thomas 201 Dissertations Abstracts International Vol/Iss: 5907B Pages: 3454 Date: 1998 Title: Steroids. L1. Aromatization reaction of the cross-conjugated dienone system by Zinc 202 Author: MORISAKI et al. 9. (Abstract only) Publ: Chem. Pharm. Bull. Vol/lss: 14 (8) Pages: 866-872 Date: 1966 203 Author: MUKHOPADHYAY et al. Title: Induction of Apoptosis in Human Lung Cancer Cells after Wild-Type p53 Activation by Methoxyestradiol Publ: Oncogene Vol/Iss: 14 Pages: 379-384 Date: 1997 Author: NAAFS et al. Title: Thalidomide Therapy An Open Trial 204 Publ-International Journal of Dermatology Vol/Iss: 24 (2) Pages: 131-134 Date: 03/1985 Author: NAKAGAWA-YAGI et al. Title: The Endogenous Estrogen Metabolite 2-Methoxyestradiol Induces Apoptotic Neurona Cell Death In Vitro Publ: <u> Life Sciences</u> Vol/Iss: 58 (17) Pages: 1461-1467 Date: 1996 Title: Studies on Steroid Conjugates. III. New Synthesis of 2-Methoxyestrogens 206 Author: NAMBARA et al. Publ: Chem. Pharm. Bulletin Vol/lss: 18 (3) Pages: 474-480 Date: 03/1970 Author: NAMBARA et al. Title: Microbial transformation products derived from steriods. I. Synthesis of 1,2- and 3-dimethoxy-4-methylestratrienes (Abstract only) Publ: Chem, Pharm. Bull. Vol/Iss: 20 (2) Pages: 336-342 Date: 1972

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